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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,066	11/17/2003	Timothy O'Brien	022438.45514	6392

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McTavish Patent Firm
429 Birchwood Courts
Birchwood, MN 55110

EXAMINER	
REDDIG, PETER J	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,066	O'BRIEN ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to an isolated nucleic acid molecule comprising the sequence of SEQ ID NO: 4 and encoding CA125, classified in class 536, subclass 23.1.

II. Claims 5-7, drawn to an isolated nucleic acid molecule comprising the sequence of SEQ ID NO: 1, classified in class 536, subclass 23.1.

III. Claims 8-10, drawn to isolated nucleic acid molecule comprising the sequence of SEQ ID NO: 2, classified in class 536, subclass 23.1.

IV. Claims 11-13, drawn to isolated nucleic acid molecule comprising the sequence of SEQ ID NO: 3, classified in class 536, subclass 23.1.

V. Claim 14, drawn to the polypeptide with the amino acid sequence selected from the group consisting of: a) the amino acid sequence set forth in SEQ ID NO: 5; (b) an amino acid sequence having at least 50% sequence identity to said sequence; (c) a conservative variant of an one of (a) to (b); and (d) a fragment of any one of (a) to (c), classified in class 530, subclass 350.

VI. Claims 15-19, drawn to a purified antibody that selectively binds to the amino acid sequence of the CA125 protein wherein the sequence comprises SEQ ID NO: 5 or variants with 50%, 60%, 70%, 80%, or 90% sequence identity to SEQ ID NO: 5, classified in class 530, subclass 387.1.

VII. Claim 20, drawn to a method to make a purified fragment of the CA125 polypeptide of SEQ ID NO: 5, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-IV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Groups I-IV are related in that they are drawn to isolated nucleic acid molecules. Although the nucleic acid molecules are related by virtue of the fact that they are all composed of nucleotides, each nucleic acid molecule is composed of different combinations of nucleotides to allow them to encode distinct structural information, i.e. they are mutually exclusive. For example, one claimed nucleic molecule of Groups I-IV could not be used in the place of the other for the production of polypeptides *in vitro* or *in vivo*.

Further, the search for all nucleic acids molecules in Groups I-IV, including the variants, would invoke a high search burden. Currently, there are approximately eight different databases that accompany the results of a search of one discrete nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of all the different sequences would require extensive searching and review in the non-patent and patent literature databases. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

The nucleic acid molecules of Groups I-IV are related to the protein of Group V by virtue of the fact that the nucleic acid molecules codes for the protein. The nucleic acid molecules molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecules and the protein are related, since the nucleic acid molecules encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, nucleic acid molecules can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of Groups I-IV and V together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups I-IV and V have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the claims include 5 distinct sequences inclusive of various homologies and fragments. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of nucleic acid molecules as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above: furthermore, a search of the nucleic acid molecules of claims 1-

13 would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group V. As such, it would be burdensome to search all of the inventions of Groups I-V.

The nucleic acid molecules of Groups I-IV and the antibody of Group VI are patentably distinct. The antibody of Group VI includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such as the antibody of Group VI which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, nucleic acid molecules of Groups I-IV will not encode the antibody of Group V, and the antibody of Group V cannot be encoded by a nucleic acid molecule of Groups I-IV. Therefore, the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group I-IV and Group VI would impose a serious search burden since a search of the nucleic acid molecules of Groups I-IV would not be used to determine the patentability of any antibody of Group VI, and vice-versa.

The polypeptide of Group V and the antibody of Group VI are patentably distinct. While the inventions of both Group V and Group VI are polypeptides, in this instance the polypeptides of Group V represent various proposed CA125 proteins, whereas the polypeptide of Group VI

encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDR) that function to bind an epitope. Thus the polypeptides of Group V and the antibodies of Group VI are structurally distinct molecules; any relationship between a polypeptide of Group V and an antibody of Group VI is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptides of group V encompass large molecules which contain potentially hundreds of regions to which an antibody may bind, whereas the antibody of Group VI is defined in terms of its binding specificity to a small structure within the sequences encompassed by claim 14. Furthermore, searching the inventions of Group V and Group VI would impose a serious search burden. The inventions have separate status in the art as shown by their different classifications. A polypeptide and an antibody that binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group VI. Furthermore, antibodies that bind to an epitope of a polypeptide of Group V may be known even if a polypeptide of Group V is novel. In addition, the technical literature search for the polypeptides of Group V and the antibody of Group VI are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The inventions of Group VII and Group V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the CA125 polypeptide could be purified from natural sources of the polypeptide, i.e. the cell or tissue where it is normally expressed. The purified CA125 could then be cleaved with proteases to generate fragments of the purified full-length protein and further purified.

Searching all of the claims of Group V and VII would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

The inventions of Groups I-IV and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acid molecule of Groups I-IV could be labeled and used as a probe in nucleic acid hybridization assays like Northern and Southern analysis for the CA125 gene.

Furthermore, searching all of the claims of Groups I-IV and Group VII would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate

field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

The inventions of Group VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the invention of Group VI is directed to a purified antibody that binds to an amino acid sequence of CA125, while the unrelated of invention of group VII is directed to a method of making a purified fragment of the CA125 polypeptide. The production of the purified antibody of group VI does not require the steps of the method of group VII designed to purify a CA125 polypeptide, not an antibody to it. Furthermore, the design and effects of the method of Group VII as claimed do not require the purified antibody of group VI.

Because the inventions of Group VI and Group VII are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

The inventions of Groups I-VII are distinct for the reasons given above and the search required for one group is not required for another group, thus restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER